

LONG-TERM CARE RECIPIENTS: QUALITY OF LIFE AND QUALITY OF CARE RESEARCH

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(<http://www.nih.gov/ninr>)

National Institute on Aging (NIA)

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National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)

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National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

(<http://www.niddk.nih.gov>)

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PURPOSE OF THIS PA

The purpose of this program announcement is to encourage research on improving the quality of life, health, functional abilities, and health outcomes for residents of long-term care (LTC) institutions such as nursing homes, extended care, and assisted living facilities. Impaired quality of life, poor functional status, and health concerns are well documented in LTC settings to have a deleterious impact on outcomes. Examples of areas of concern include, but are not limited to, poor nutrition, impaired oral health, diabetes related hyperglycemia and hypoglycemia, renal dialysis, impaired mobility, management of acute and chronic health conditions, and decreased social interactions. Research is also needed for understudied age groups, ethnic groups, and for certain health conditions. The goals of this PA are to stimulate clinical research to advance knowledge about long-term care populations and to encourage testing of interventions to improve quality of life, health, and functional status of long-term care residents. Another important goal of this PA is to encourage studies of interventions that can be translated into practice in current LTC environments.

RESEARCH OBJECTIVES

There are approximately 2 million nursing home residents and over 1.5 million people in assisted living facilities and homes for adults. These numbers are expected to double by the year 2020. Currently, at least 40% of the population over age 75 is predicted to need extensive health care services late in their lives. Long-term care is also needed for many younger adults and children who have chronic disabling physical or mental disabilities or who have non-permanent conditions requiring LTC. Care needs are often related to the development of disabling conditions such as multiple sclerosis, stroke, complications of diabetes, or trauma. Moreover, with increasing life expectancies, individuals with disabling health conditions are likely to spend a longer period of time in long-term care facilities. The complexity of health care is also likely to increase with science advances, longevity, and increases in chronic disease prevalence and incidence.

Health care and quality of life issues in long-term care can be expected to grow as "baby boomers" reach 65 years and older, as the proportion of individuals over 85 continues to increase, and as other health-related disabilities and chronic diseases continue to affect all age groups.

The Federal Interagency Forum on Aging-Related Statistics, in a published report titled Older Americans 2000: Key Indicators of Well-Being, noted that the racial and ethnic makeup of the U.S. is changing, including that within the older population. At the time of the report, about 84 percent of the population age 65 and older was non-Hispanic white with minority ethnic groups making up the remaining 16 percent. These proportions are projected to change significantly by

2050. The projections for older adults are that non-Hispanic whites will make up 64 percent of the population while minority ethnic groups will increase to 36 percent of the population. This continuing change in the ethnic/racial makeup of the U.S. may have an impact on many health areas, including approaches to long-term care. For example, population groups may differ by access, utilization, health behaviors, family involvement, and personal views about LTC. Studies are needed on the use of existing data in LTC settings to bring about continuing improvements in health outcomes and quality of life.

The continuing increase in lifespan for the U.S. population, including those with chronic diseases or disabilities that require long-term care will create a demand for more and improved quality of long-term care. While older adults are healthier than ever, there continues to be large numbers of older people with chronic conditions and disabilities, especially at very advanced ages, along with cognitive impairments and depression, all of which can substantially diminish quality of life and functional status.

Traditionally, LTC institutions have been identified as nursing homes. During the past 20 – 30 years, additional kinds of LTC facilities have evolved. Assisted living facilities, for example, are a fast growing segment for long-term care. Alternative living arrangements for dependent older adults, the mentally ill, and mentally handicapped individuals are becoming more prevalent. Little research has been done on assisted living and other alternative LTC populations and how they may differ from nursing home populations in quality of life and health outcomes and whether adaptations to setting are required for health care interventions.

Serious problems with health care, including nursing home care, have been well documented during the past ten years. The Institute of Medicine (IOM) concluded, in a 2000 executive summary report, that although positive changes had occurred in long-term care since the 1986 IOM study, the quality of life for nursing home residents improved only slightly, and serious problems remain. Noted health care problems in nursing homes include pain, pressure sores, malnutrition, and urinary incontinence.

Common problems experienced by LTC recipients continue to have a strong impact on their health status across the U.S. Problem areas in LTC that are well documented include impairment in the following areas: nutrition and hydration, functional status, falls and injuries, cognitive function, medication management, physical activity and mobility, bowel and urine continence, susceptibility to infection, vulnerability to depression, health maintenance, social engagement, and family involvement. In addition to current knowledge, questions remain about whether

intervention effectiveness for these problem areas varies by diverse cultural and ethnic LTC groups.

The prevalence of depression in older adults in long-term care settings clearly impacts quality of life. Depression that occurs after placement in long-term care implies that there are influencing factors that may be amenable to change. The cause of depression in LTC residents is not fully understood and whether it is related to adaptation to change, the loss of independence, health care management, LTC experiences, loss of association with family members, or to multiple factors needs to be determined. Further research is needed to address these issues.

Quality of life in long-term care institutions is affected by, among other things, the physical, social, and health care environments. The physical environment impacts on quality of life throughout daily experiences such as the need to feel safe and secure during physical activity or activities of daily life, including, for example, mealtime, personal and oral hygiene, and recreational activities. The social environment affects quality of life from many aspects. The ability to maintain as much independence as possible and to continue to make immediate daily life and health care choices is important to supporting quality of life. Passive health care maintenance rather than dynamic, proactive health care for older adults and for debilitated individuals of any age has been identified as occurring when staff or decision makers view the individual as "too old" or "too sick" for new medical or dental advances resulting in poor quality of life during the person's final years of life.

Positive social engagement with LTC staff, other residents, and family members and friends has been shown to improve the quality of life for LTC recipients. Research is needed to develop and test strategies to facilitate ongoing social engagement over time.

A recent GAO report notes an unacceptable level of physical and sexual abuse in nursing homes. Studies are needed to identify precipitating factors and how to prevent such occurrences.

The physical health and safety of LTC residents is an ongoing concern. Common goals are to maintain and improve health, to prevent injury or illness, and to facilitate a high quality of life for residents. These goals are difficult to achieve when the care environment leads to poor nutrition and hydration, and a compromised health state. Infections such as pneumonia or tuberculosis are more prevalent when the normal physiological and immunological protections are compromised. Although there is a progression of some illnesses and health conditions that cannot be reversed, a slowing or reversal of such conditions may be a feasible goal.

Long-term care residents may have multiple chronic conditions that require vigilance and daily monitoring. Frailty or impaired functional abilities of residents may prevent active self-management of their own health conditions as perhaps they once did. Strategies that promote participation in self-care and decision making to the resident's potential are important research topics, as are interventions that promote and maintain functional abilities.

Interventions that promote more effective and efficient monitoring of health status and therapeutic, timely interventions for chronic and acute health problems are needed in tight economic and current staffing environments.

Understudied LTC populations include those in rural nursing homes, ethnic minority populations in significant numbers for meaningful analysis, and residents without involved family or friends. All populations, but these groups in particular, need additional study for interventions that are cross-cutting and identifications of interventions that lend themselves to adaptation to different groups or settings.

Scope

Responses to this announcement will focus on research opportunities for the growing population of institutionalized long-term care recipients. Another program announcement, PA02-155, titled Informal Caregiving Research For Chronic Conditions, focuses on caregiving for non-institutionalized care recipients. LTC institutions of interest are nursing homes, assisted living facilities, and alternative LTC sites. Studies of all ethnic/racial populations and age groups are of interest. Exploratory studies in new or understudied areas such as those just noted are encouraged. Studies are particularly encouraged that 1) test promising new or improved interventions for long-standing LTC resident health or quality of life concerns and 2) test effective interventions in understudied populations. Of particular interest are innovative approaches that are evaluated for effectiveness within the current long-term care infrastructure and with current fiscal constraints.

Potential Research Areas:

The following research topics are provided as examples that would extend current research. The topics are not listed in any priority order and are not intended to be inclusive or restrictive. All responsive applications, regardless of design or target group, must display awareness of and sensitivity to cultural or race/ethnic/gender issues in appropriate components of the study.

- o Determine social, cognitive, psychosocial, cultural, race/ethnic, and other personal factors that influence or mediate residents' health or quality of life.
- o Identify staffing, environmental, and biotechnological factors that enhance quality of life and improve health outcomes.
- o Test interventions aimed at decreasing falls and injuries, preventing or reducing oral and other infections, improving medication management and pain and other areas of symptom management.
- o Examine interventions to increase functional mobility, physical activity, and restful sleep.
- o Test interventions to maintain or improve health factors related to skin integrity, nutrition, hydration, dentition and oral function, and continence.
- o Assess methods to improve and maintain social engagement and cognitive stimulation in the LTC setting with a focus on long-term, integrated change.
- o Examine methods to facilitate family and friends' involvement in the LTC resident's life experiences to enhance quality of life and health outcomes.
- o Test interventions to effectively manage acute (bone fractures, infection) and single or multiple chronic illnesses (diabetes, stroke, arthritis, cancer, AIDS) and to prevent complications such as pressure ulcers, contractions, pneumonia, and other infections.
- o Identify strategies to more effectively manage depression, agitation, and confusion and to facilitate emotional and social support in diverse health conditions.
- o Examine physical, therapeutic, and social environments that enhance quality of care and resident satisfaction and social participation. A few examples may include selection of roommates, the proximity of residents, and the volume of radios and televisions.
- o Identify factors that facilitate psychosocial adjustment and adaptation to long-term care facilities for both residents and their family and friends.
- o Test the effectiveness of LTC interventions by various ethnic or cultural populations, age, gender, and cognitive status.
- o Assess methods that enhance resident participation in decision making about their care management and daily lifestyle to the level desired by the resident.
- o Develop studies focusing on younger LTC populations, i.e., youth and adults under 65 years, quality of life, and health status problems.
- o Explore strategies to maximize LTC facilities' utilization of findings or expertise from existing research centers in academic and clinical settings to enhance quality of life, quality of care, and health outcomes. Examples may include research knowledge, evidence-based protocols, or processes and strategies to implement best practices.

MECHANISMS OF SUPPORT

This PA will use the NIH R01 and R21 award mechanisms. As an applicant, you will be solely responsible for planning, directing, and executing the proposed project. The objective of the exploratory/developmental mechanism (R21) is to encourage applications from individuals who are interested in testing innovative or conceptually creative ideas that are scientifically sound and may advance our understanding of quality of life issues in long term care. Investigators are encouraged to explore the feasibility of an innovative research question or approach that will provide a basis for future research project applications. Exploratory/developmental grants (R21) are limited to 2 years of support and up to \$150,000 per year in direct costs. Application page limits differ according to mechanism. Please see the "Submitting an Application" section for more details.

This PA uses just-in-time concepts. It also uses the modular and non-modular budgeting formats. (see <http://grants.nih.gov/grants/funding/modular/modular.htm>). Specifically, if you are submitting an application with direct costs in each year of \$250,000 or less, use the modular format. Otherwise, use the standard PHS 398 instructions for detailed budgets.

ELIGIBLE INSTITUTIONS

You may submit (an) application(s) if your institution has any of the following characteristics:

- o For-profit or non-profit organizations
- o Public or private institutions, such as universities, colleges, hospitals, and laboratories
- o Units of State and local governments
- o Eligible agencies of the Federal government
- o Domestic or foreign
- o Faith-based or community based organizations

INDIVIDUALS ELIGIBLE TO BECOME PRINCIPAL INVESTIGATORS

Any individual with the skills, knowledge, and resources necessary to carry out the proposed research is invited to work with their institution to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH programs

WHERE TO SEND INQUIRIES

We encourage your inquiries concerning this PA and welcome the opportunity to answer questions from potential applicants. Inquiries may fall into two areas: scientific/research and financial or grants management issues:

o Direct your questions about scientific/research issues to:

Dr. Nell Armstrong
Office of Extramural Programs
National Institute of Nursing Research
6701 Democracy Blvd, Room 710, MSC 4870
Bethesda, MD 20892-4870
Telephone: (301) 594-5973
FAX: (301) 480-8260
Email: nell.armstrong@nih.gov

Dr. Sidney M. Stahl
Chief, Behavioral Medicine
National Institute on Aging
7201 Wisconsin Ave., #533
Bethesda, MD 20892-9205
Telephone: (301) 402-4156
FAX: (301) 402-0051
Email: Sidney_Stahl@nih.gov

Dr. Deborah N. Ader
Director, Behavioral and Prevention Research Program
National Institute of Arthritis and Musculoskeletal and Skin Diseases
One Democracy Plaza
6701 Democracy Boulevard, Suite 800, MSC 4872
Bethesda, MD 20872-4872
Tel: (301) 594-5032
Fax: (301) 480-4543
Email: deborah_ader@nih.gov

Dr. Louis Quatrano
Behavioral Sciences and Rehabilitation Engineering
National Institute of Child Health and Human Development

6100 Executive Boulevard, 2A03, MSC 7510

Bethesda, MD 20892-7510

Telephone: (301) 402-4221

FAX: (301) 496-0832

Email: quatranl@exchange.nih.gov

Dr. Patricia Bryant

Program Director

Behavioral and Social Science Research Program

Division of Population and Health Promotion Sciences

National Institute of Dental and Craniofacial Research

Natcher Bldg Room 4AN24E

45 Center Drive MSC6402

Bethesda, MD 20892-6402

Telephone: (301) 594-2095

FAX: (301) 480-8318

Email: Patricia.Bryant@nih.gov

Dr. Sanford Garfield

Senior Advisor for Biometry &

Behavioral Research

National Institute of Diabetes & Digestive & Kidney Diseases

Two Democracy Plaza, Room 685

6707 Democracy Blvd

Bethesda, MD 20892-5460

Phone: (301) 594-8803

FAX: (301) 402-6271

E-mail: garfields@extra.niddk.nih.gov

o Direct your questions about financial or grants management matters to:

Ms. Diane Drew

Office of Grants and Contracts Management

National Institute of Nursing Research

6701 Democracy Blvd, Room 710, MSC 4870

Bethesda, MD 20892-4870

Telephone: (301) 594-2807

FAX: (301) 451-5651

Email: diane_drew@nih.gov

Ms. Grace Poe

Grants and Contracts Management Office

National Institute on Aging

7201 Wisconsin Ave., #212

Bethesda, MD 20892-9205

Phone: (301) 496-1472

FAX: (301) 402-3672

Email: Poeg@mail.nih.gov

Ms. Melinda Nelson

Grants Management Officer

National Institute of Arthritis and Musculoskeletal and Skin Diseases

One Democracy Plaza

6701 Democracy Boulevard, Suite 800, MSC 4872

Bethesda, MD 20872-4872 Telephone: (301) 594-3535

FAX: (301) 480-5450

Email: melinda_nelson@nih.gov

Mr. Christopher Myers

Grants Management Branch

National Institute of Child Health and Human Development

6100 Executive Boulevard, 8A17, MSC 7510

Telephone: (301) 435-6996

FAX: (301) 402-0915

Email: cm143g@nih.gov

Ms. Florence Danshes

Grants Management Specialist

National Institute of Diabetes & Digestive & Kidney Diseases

Two Democracy Plaza, Room 734

6707 Democracy Blvd

Bethesda, MD 20892-5456

Phone: (301) 594-8861

FAX: (301) 480-3504

Email: danshesf@extra.niddk.nih.gov

SUBMITTING AN APPLICATION

Applications must be prepared using the PHS 398 research grant application instructions and forms (rev. 5/2001). The PHS 398 is available at <http://grants.nih.gov/grants/funding/phs398/phs398.html> in an interactive format. For further assistance contact GrantsInfo, Telephone (301) 435-0714, Email: GrantsInfo@nih.gov.

Please note, when completing an application for the R21 mechanism, Items a-d in the Research Plan must not exceed a total of 15 pages. Tables and figures are included in the page limitations. The 15-page limitation does not include Items e-i (Human Subjects, Vertebrate Animals, Literature Cited, Consortia and Consultants/Collaborators).

APPLICATION RECEIPT DATES: Applications submitted in response to this program announcement will be accepted at the standard application deadlines, which are available at <http://grants.nih.gov/grants/dates.htm>. Application deadlines are also indicated in the PHS 398 application kit.

SPECIFIC INSTRUCTIONS FOR MODULAR GRANT APPLICATIONS: Applications requesting up to \$250,000 per year in direct costs must be submitted in a modular grant format. The modular grant format simplifies the preparation of the budget in these applications by limiting the level of budgetary detail. Applicants request direct costs in \$25,000 modules. Section C of the research grant application instructions for the PHS 398 (rev. 5/2001) at <http://grants.nih.gov/grants/funding/phs398/phs398.html> includes step-by-step guidance for preparing modular grants. Additional information on modular grants is available at <http://grants.nih.gov/grants/funding/modular/modular.htm>.

SPECIFIC INSTRUCTIONS FOR APPLICATIONS REQUESTING \$500,000 OR MORE PER YEAR:

Applications requesting \$500,000 or more in direct costs for any year must include a cover letter identifying the NIH staff member within one of NIH institutes or centers who has agreed to accept assignment of the application.

Applicants requesting more than \$500,000 must carry out the following steps:

Contact the IC program staff at least 6 weeks before submitting the application, i.e., as you are developing plans for the study;

2) Obtain agreement from the IC staff that the IC will accept your application for consideration for award; and,

3) Identify, in a cover letter sent with the application, the staff member and IC who agreed to accept assignment of the application.

This policy applies to all investigator-initiated new (type 1), competing continuation (type 2), competing supplement, or any amended or revised version of these grant application types. Additional information on this policy is available in the NIH Guide for Grants and Contracts, October 19, 2001 at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-004.html>.

SENDING AN APPLICATION TO THE NIH: Submit a signed, typewritten original of the application, including the checklist, and five signed photocopies in one package to:

Center for Scientific Review
National Institutes of Health
6701 Rockledge Drive, Room 1040, MSC 7710
Bethesda, MD 20892-7710
Bethesda, MD 20817 (for express/courier service)

APPLICATION PROCESSING: Applications must be received by or mailed on or before the receipt dates described at <http://grants.nih.gov/grants/funding/submissionschedule.htm>. The CSR will not accept any application in response to this PA that is essentially the same as one currently pending initial review unless the applicant withdraws the pending application. The CSR will not accept any application that is essentially the same as one already reviewed. This does not preclude the submission of a substantial revision of an application already reviewed, but such application must include an Introduction addressing the previous critique.

PEER REVIEW PROCESS

Applications submitted for this PA will be assigned on the basis of established PHS referral guidelines. An appropriate scientific review group convened in accordance with the standard NIH peer review procedures (<http://www.csr.nih.gov/refrev.htm>) will evaluate applications for scientific and technical merit.

As part of the initial merit review, all applications will:

- o Receive a written critique
- o Undergo a selection process in which only those applications deemed to have the highest scientific merit, generally the top half of applications under review, will be discussed and assigned a priority score
- o Receive a second level review by the appropriate national advisory council or board

REVIEW CRITERIA

The goals of NIH-supported research are to advance our understanding of biological systems, improve the control of disease, and enhance health. In the written comments, reviewers will be asked to discuss the following aspects of your application in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these goals:

- o Significance
- o Approach
- o Innovation
- o Investigator
- o Environment

The scientific review group will address and consider each of these criteria in assigning your application's overall score, weighting them as appropriate for each application. Your application does not need to be strong in all categories to be judged likely to have major scientific impact and thus deserve a high priority score. For example, you may propose to carry out important work that by its nature is not innovative but is essential to move a field forward.

(1) SIGNIFICANCE: Does your study address an important problem? If the aims of your application are achieved, how do they advance scientific knowledge? What will be the effect of these studies on the concepts or methods that drive this field?

(2) APPROACH: Are the conceptual framework, design, methods, and analyses adequately developed, well integrated, and appropriate to the aims of the project? Do you acknowledge potential problem areas and consider alternative tactics?

(3) INNOVATION: Does your project employ novel concepts, approaches or methods? Are the aims original and innovative? Does your project challenge existing paradigms or develop new methodologies or technologies?

(4) INVESTIGATOR: Are you appropriately trained and well suited to carry out this work? Is the work proposed appropriate to your experience level as the principal investigator and to that of other researchers (if any)?

(5) ENVIRONMENT: Does the scientific environment in which your work will be done contribute to the probability of success? Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support?

ADDITIONAL REVIEW CRITERIA: In addition to the above criteria, your application will also be reviewed with respect to the following:

PROTECTIONS: The adequacy of the proposed protection for humans, animals, or the environment, to the extent they may be adversely affected by the project proposed in the application.

INCLUSION: The adequacy of plans to include subjects from both genders, all racial and ethnic groups (and subgroups), and children as appropriate for the scientific goals of the research. Plans for the recruitment and retention of subjects will also be evaluated. (See Inclusion Criteria included in the section on Federal Citations, below)

DATA SHARING: The adequacy of the proposed plan to share data.

BUDGET: The reasonableness of the proposed budget and the requested period of support in relation to the proposed research.

AWARD CRITERIA

Applications submitted in response to a PA will compete for available funds with all other recommended applications. The following will be considered in making funding decisions:

- o Scientific merit of the proposed project as determined by peer review
- o Availability of funds

- o Relevance to program priorities

REQUIRED FEDERAL CITATIONS

MONITORING PLAN AND DATA SAFETY AND MONITORING BOARD: Research components involving Phase I and II clinical trials must include provisions for assessment of patient eligibility and status, rigorous data management, quality assurance, and auditing procedures. In addition, it is NIH policy that all clinical trials require data and safety monitoring, with the method and degree of monitoring being commensurate with the risks (NIH Policy for Data Safety and Monitoring, NIH Guide for Grants and Contracts, June 12, 1998:

<http://grants.nih.gov/grants/guide/notice-files/not98-084.html>).

INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH: It is the policy of the NIH that women and members of minority groups and their sub-populations must be included in all NIH-supported clinical research projects unless a clear and compelling justification is provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43).

All investigators proposing clinical research should read the AMENDMENT "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research - Amended, October, 2001," published in the NIH Guide for Grants and Contracts on October 9, 2001 (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html>); a complete copy of the updated Guidelines are available at http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm.

The amended policy incorporates: the use of an NIH definition of clinical research; updated racial and ethnic categories in compliance with the new OMB standards; clarification of language governing NIH-defined Phase III clinical trials consistent with the new PHS Form 398; and updated roles and responsibilities of NIH staff and the extramural community. The policy continues to require for all NIH-defined Phase III clinical trials that: a) all applications or proposals and/or protocols must provide a description of plans to conduct analyses, as appropriate, to address differences by sex/gender and/or racial/ethnic groups, including subgroups if applicable; and b) investigators must report annual accrual and progress in conducting analyses, as appropriate, by sex/gender and/or racial/ethnic group differences.

INCLUSION OF CHILDREN AS PARTICIPANTS IN RESEARCH INVOLVING HUMAN SUBJECTS:

The NIH maintains a policy that children (i.e., individuals under the age of 21) must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them. This policy applies to all initial (Type 1) applications submitted for receipt dates after October 1, 1998.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines" on the inclusion of children as participants in research involving human subjects that is available at <http://grants.nih.gov/grants/funding/children/children.htm>.

REQUIRED EDUCATION ON THE PROTECTION OF HUMAN SUBJECT PARTICIPANTS: NIH policy requires education on the protection of human subject participants for all investigators submitting NIH proposals for research involving human subjects. You will find this policy announcement in the NIH Guide for Grants and Contracts Announcement, dated June 5, 2000, at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html>.

PUBLIC ACCESS TO RESEARCH DATA THROUGH THE FREEDOM OF INFORMATION ACT: The Office of Management and Budget (OMB) Circular A-110 has been revised to provide public access to research data through the Freedom of Information Act (FOIA) under some circumstances. Data that are (1) first produced in a project that is supported in whole or in part with Federal funds and (2) cited publicly and officially by a Federal agency in support of an action that has the force and effect of law (i.e., a regulation) may be accessed through FOIA. It is important for applicants to understand the basic scope of this amendment. NIH has provided guidance at http://grants.nih.gov/grants/policy/a110/a110_guidance_dec1999.htm.

Applicants may wish to place data collected under this PA in a public archive, which can provide protections for the data and manage the distribution for an indefinite period of time. If so, the application should include a description of the archiving plan in the study design and include information about this in the budget justification section of the application. In addition, applicants should think about how to structure informed consent statements and other human subjects procedures given the potential for wider use of data collected under this award.

URLs IN NIH GRANT APPLICATIONS OR APPENDICES: All applications and proposals for NIH funding must be self-contained within specified page limitations. Unless otherwise specified in an NIH solicitation, Internet addresses (URLs) should not be used to provide information necessary to the review because reviewers are under no obligation to view the Internet sites. Furthermore, we caution reviewers that their anonymity may be compromised when they directly access an Internet site.

HEALTHY PEOPLE 2010: The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a PHS-led national activity for setting priority areas. This PA is related to one or more of the priority areas. Potential applicants may obtain a copy of "Healthy People 2010" at <http://www.health.gov/healthypeople>.

AUTHORITY AND REGULATIONS: This program is described in the Catalog of Federal Domestic Assistance No. 93.361 (NINR), 93.866 (NIA), 93.846 (NIAMS), 93.929 (NICHD), 93.121 (NIDCR) 93.847 and 93.879 (NIDDK), and is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review. Awards are made under authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284 and administered under NIH grants policies described at <http://grants.nih.gov/grants/policy/policy.htm> and under Federal Regulations 42 CFR 52 and 45 CFR Parts 74 and 92.

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and discourage the use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

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